

Attorney Docket No.: P-633 (TI-0020)
Inventors: Taylor and Yu
Serial No.: 09/873,645
Filing Date: June 4, 2001
Page 5

REMARKS

Claims 13-16 are pending in the instant application. Claims 13-16 have been rejected. Claim 13 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejections under 35 U.S.C §§ 101 and 112

Claims 13-16 have been rejected under 35 U.S.C. 101 because it is suggested that the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility. The Examiner acknowledges that the specification provides a utility for utilizing the shifted profiles to generate values that are utilized for comparison to controls in order to detect mutations; however, it is suggested that the specification does not set forth an asserted utility for merely shifting profiles that can be used to group elution profiles. The Examiner suggests that one of skill in the art would not know what to do with the elution profiles generated, as there is no specification utility set forth for the profiles themselves.

Claims 13-16 have also been rejected under 35 U.S.C. 112, first paragraph, as it is suggested that since the claimed invention is not supported by a specific, substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully traverse these rejections.

Attorney Docket No.: **P-633 (TI-0020)**
Inventors: **Taylor and Yu**
Serial No.: **09/873,645**
Filing Date: **June 4, 2001**
Page 6

MPEP §2106 indicates that the claimed invention as a whole must accomplish a practical application to satisfy the utility requirement. That is, it must produce a "useful, concrete and tangible result." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02. In this regard, page 16 (lines 4-16) of the disclosure indicates that the practical application of the claimed invention is

"for analyzing chromatograms obtained from the DMIPC analysis of samples containing hybridized DNA fragments; for transforming all of the chromatograms obtained from the analysis of a plurality of samples so that they can be viewed and analyzed in a standardized format; for grouping the adjusted profiles based on their shape or pattern. The invention can be used to determine the number and identity of SNPs in the samples by considering characteristics of the grouped profiles. The invention includes methods and devices for facilitating the comparison of DMIPC elution profiles so that they can be more readily interpreted; for grouping the profiles based on their shapes; and for determining whether a plurality of profiles represents more than one group of profiles."

Applicants further explain the relative significance of the invention in the paragraph spanning page 24 and page 25, indicating that:

"[i]t is impractical to identify groups of similar profiles using raw data as shown in FIGS. 5, 7, 8, and 21 due to slight run-to-run variations in baseline drift, detector signal noise, and retention time. These variations can be due to such factors as contamination of the separation column and changes in the composition of the mobile phase buffers (such as by evaporation of acetonitrile). The present invention is based in part on Applicants unexpected observation

Attorney Docket No.: **P-633 (TI-0020)**
Inventors: **Taylor and Yu**
Serial No.: **09/873,645**
Filing Date: **June 4, 2001**
Page 7

that when steps are taken [to] transform the profiles obtained from DMIPC analysis, in order to correct for such variations, that groups of profiles can be observed. These groups can be used in determining the presence and identity of mutations in the DNA being analyzed."

Applicants disclose the process of the present invention (see page 28, line 7, to page 31, line 22) and exemplify the same by adjusting the signal data and time data of 96 chromatographic elution profiles to provide a usable format for viewing and analysis (see Example 1). Figure 22 shows the elution profiles of the 96 chromatograms presented in Figure 21 within a selected time span after being subjected to the process of the claimed system (see page 42, lines 26-29). Based upon this adjustment, Applicants could readily separate the 96 profiles into two groups, wild-type (Figure 23) and G>A mutation (Figure 24). See the paragraph spanning pages 42 and 43 and Figure legends for Figures 23 and 24 at pages 15 and 16, respectively. In view of this exemplification and the teachings of the specification, one of skill in the art could readily recognize the practical application of plotting data sets, selecting time points, adjusting a baseline, normalizing peaks, and shifting profiles as facilitating the viewing and analysis of the DMIPC data sets to detect mutations.

Thus, given that the specification clearly provides a specific, substantial asserted utility for the claimed system for computer implemented adjustment of signal data and time data of a plurality of chromatographic elution profiles; the Examiner has acknowledged that the specification provides "a utility for

Attorney Docket No.: P-633 (TI-0020)
Inventors: Taylor and Yu
Serial No.: 09/873,645
Filing Date: June 4, 2001
Page 8

utilizing the shifted profiles to generate values that are utilized for **comparison** to controls in order to detect mutations;" and Applicants have exemplified mutant detection using the claimed invention, the utility and enablement requirements of §§ 101 and 112, first paragraph, have been met. It is therefore respectfully requested that these rejections be reconsidered and withdrawn.

Claims 13-16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, claim 13 has been rejected for reciting "shifting each of the profiles along said first axis such that all of the profiles intersect at a pre-selected point on the last eluting peak of each profile within said time span so that the values from the plurality of chromatographic elution profiles can be used to group the plurality of chromatographic elution profiles." The Examiner suggests that it is unclear whether the processor is grouping the elution profiles or if the process is shifting the profiles. It is suggested that grouping appears to be an intended result and clarification is requested. The Examiner has requested clarification. Applicants respectfully disagree with this rejection.

In an earnest effort to facilitate the prosecution of this application, Applicants have amended claim 13, removing the phrase "so that the values from the plurality of chromatographic elution profiles can be used to group the plurality of chromatographic elution profiles" and indicating that the result

Attorney Docket No.: P-633 (TI-0020)
Inventors: Taylor and Yu
Serial No.: 09/873,645
Filing Date: June 4, 2001
Page 9

of plotting data sets, selecting time points, adjusting a baseline, normalizing peaks, and shifting profiles is to adjust the signal and time data of a plurality of chromatographic elution profiles. Support for this amendment is found in the preamble of the claim. In light of this amendment, reconsideration and withdrawal of this rejection is respectfully requested.

II. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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